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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,853	10/17/2007	Katsumi Aoyagi	053466-416	4864

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,853	Applicant(s) AOYAGI ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 8-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5 lists</u> . | 6) <input checked="" type="checkbox"/> Other: <u>pages 23-26 of 09/269897</u> . |

DETAILED ACTION

1. Claims 1-23 are pending in the application.

Election/Restrictions

2. Applicant's election without traverse of Group I, the species wherein the method comprises the treatment sample with an acidifying agent, an amphoteric substrate (esp. N-tetradecyl-N,N-dimethyl-3-ammonio-1-propanesulfanate), and a cationic surfactant (esp. decyltrimethylammonium bromide) in the reply filed on November 6, 2009 is acknowledged.

3. Claims 2, 3, and 8-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species or inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 6, 2009.

It is noted that, while the Applicant asserts that each of claims 1-7 read on the elected invention, claims 2 and 3 require the treatment of the sample with additional, or with a different combination of, compounds from the elected species.

4. Claims 1 and 4-7 are under consideration.

Information Disclosure Statement

5. The information disclosure statements (IDS) submitted on August 31, 2006, February 11 and March 23, 2008, and May 5 and August 24, 2009 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Only the abstract of the following reference has been submitted. The reference has therefore been considered only to the extent of that abstract.

Art Unit: 1648

Huebner et al., reference E4 in the Aug 2009 IDS.

The following references are in a foreign language, have been considered to the extent of the English language abstracts or documents explaining their relevance.

EP 1039297 in the August 2009 IDS.

References C7 and C8 in the April 2008 IDS.

Reference B1 of the February 2008 IDS.

References A1-A6 of the August 2006 IDS.

The following reference is in a non-English language, and has therefore not been considered.
Reference D1 in the May 2009 IDS.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, and 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is treated as representative. The claim recites the limitation "the HCV antigen" in lines 6 and 7 of the claim. There is insufficient antecedent basis for this limitation in the claim. The claim previously referred to a HCV- containing sample. It is not clear if the HCV antigen referred to later in the claim is intended to be the HCV particle itself, or if it may be any HCV antigen.

Further, it appears that the intent of the claimed methods is to render methods for the detection of HCV antigens more sensitive. Thus, it would appear that the samples being tested are not known to contain HCV antigens, but are merely suspected of containing such antigens.

It is therefore recommended that claim 1 be amended in lines 1 and 2 to refer to - - treating samples to be tested for the presence of HCV antigens which comprise treating the samples- - according to the disclosed and claimed method.

Art Unit: 1648

In addition, because it appears that the claims are intended to read on the detection of HCV antigens in samples as a means for determining their presence, without requiring prior knowledge of the presence of such antigens, it is also recommended that subpart (s) of claim 4 be amendment to read - - determining if HCV antigen is present using a probe that binds to the HCV antigen.- -

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoyanagi et al. (JP 11051940 - of record in the August 2006 IDS). These claims are drawn to methods of treating HCV containing samples with an acidifying agent (such as hydrochloric acid) and a protein denaturing agent. Claims 4 requires the further detection of an HCV antigen in the treated sample using a probe that binds thereto (such as an antibody). Such a method is disclosed by the abstract of the indicated reference. The reference therefore anticipates the indicated claims.

10. Claims 1, and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoyagi II et al. (WO 99/16836). These claims are drawn to methods of treating HCV containing samples with an acidifying agent (such as hydrochloric acid) and an amphoteric surfactant (such as dodecyltrimethylammonio propanesulfonate). The Aoyagi II reference also teaches methods for improving the sensitivity of an assay for HCV antigens. See e.g., abstract, and pages 23-26 of

Art Unit: 1648

application 09/269897 (representing a translation of relevant portions of the Aoyagi II reference-attached as an appendix to the present application). This reference teaches the pretreatment of samples with a combination of an acidifying agent such as hydrochloric acid, a surfactant, and an additional agent. See e.g., translation as found on page 25. Among the surfactants identified as useful in the acid treatment step is the amphoteric surfactant dodecyldimethylammino propanesulfate. Pages 25-26. The reference therefore anticipates the indicated claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyagi et al. (WO 00/07023- teachings referenced as translated in US 7,316,905) and Aoyagi et al. (Aoyagi II, WO 99/16836). These claims are drawn to methods of treating HCV containing samples with an acidifying agent (such as hydrochloric acid) and with an amphoteric or cationic surfactant having both a straight (linear) alkyl group of 10 or more carbon atoms and a tertiary or quaternary ammonium salt (amine). Claims 6 and 7 identify, respectively, potential amphoteric and cationic surfactants according to claim 1 that may be used to treat the sample.

Aoyagi teaches a method for the detection of HCV antigens in a sample comprising introducing the sample into conditions that comprise one or more detergents, preferable

Art Unit: 1648

comprising a linear alkyl chain with 10 or more carbon atoms, and preferable containing a tertiary or quaternary amine; and using an antibody to the antigen to detect the presence of the antigen. Columns 6-7, esp. col 7 lines 25-48. The reference provides examples of both cationic and amphoteric detergents that may be used in such methods in lines 39-48 of column 7, which examples include or render obvious several of those presented in present claims 6 and 7. The reference teaches that these detergents are used for the purpose of However, the reference does not teach or suggest the pre-treatment of the samples with an acidifying agent.

Like Aoyagi, the Aoyagi II reference also teaches methods for improving the sensitivity of an assay for HCV antigens. See e.g., abstract, and pages 23-26 of application 09/269897 (representing a translation of relevant portions of the Aoyagi II reference- attached as an appendix to the present application). This reference teaches the pretreatment of samples with a combination of an acidifying agent such as hydrochloric acid, a surfactant, and an additional agent. See e.g., translation as found on page 25. Among the surfactants identified as useful in the acid treatment step is the amphoteric surfactant dodecyldimethylammino propanesulfate. Pages 25-26. This surfactant is also among those disclosed in claim 6, and those identified in the Aoyagi reference (column 7, lines 34-48) as useful for the same purpose as in the Aoyagi II reference.

In view of the above, it would have been obvious to those of ordinary skill in the art to combine the steps of treating the samples with the acidifying agent and surfactants of Aoyagi II with the treatment of the samples with the detergents of Aoyagi for the purpose of reducing the number of agents required, and the number of steps being used to treat the samples. I.e., it would have been obvious to those of ordinary skill in the art to pre-treat the samples with all of the

Art Unit: 1648

acidifying agent, surfactant, and additional agent of Aoyagi II, using the amphoteric surfactants of Aoyagi as the surfactant. Because Aoyagi indicates that the detergents may be combined to provide synergistic results, it would have been obvious to those of ordinary skill in the art to use the amphoteric surfactant either alone or in combination with a cationic surfactant of Aoyagi.

Thus, the presently claimed methods would have been obvious to those of ordinary skill in the art based on the combination of the teachings of these references.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

Art Unit: 1648

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648